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09/18/2006

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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/568248
Filing Date: 09/18/2006
Appellant(s): Peuker et al.

Peter L. Olson
For Appellant

EXAMINER'S ANSWER

This is in response to the Appeal Brief filed 06/23/2010 appealing from the Office Action mailed 02/26/2010.

Art Unit: 3732

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 51-89 are pending.

Claims 65-81 and 85-88 are withdrawn.

Claims 51-64, 82-84, and 89, are rejected and are the subject of this appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

Art Unit: 3732

REJECTIONS.” New grounds of rejection (if any) are provided under the subheading “NEW GROUNDS OF REJECTION.”

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 5,743,436	WILCOX ET AL.	04-1998
US 6,048,201	ZWINGENBERGER	04-2000
US 2004/0262332 A1	PAUSER ET AL.	12-2004
US 6,572,031	HUNTER ET AL.	06-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

- i. **Claims 51, 53-54, 82-84, and 89, are rejected under 35 U.S.C. 102(b) as anticipated by Wilcox et al. (5,743,436) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilcox et al. in view of Zwingenberger (6,048,201).**

Regarding claim 51, Wilcox et al. disclose a unit-dose syringe (Figs. 1-4) comprising: a cartridge 12 having front and rear ends (best shown as 52 and 51 in Fig. 4) and a compartment 50 for each component; a static mixer 56 connectable with said cartridge at its front end, a mixing tip 54 being integrally connected to the cartridge at said front end of said cartridge and receiving said static mixer, said mixing tip and said cartridge being integrally formed as one part (Fig. 4). The syringe further comprises a plunger 42 being located in the inactivated state of the

Art Unit: 3732

syringe, at said rear end of said cartridge, and movable towards the front end of said cartridge for dispensing material from said cartridge through said mixing tip.

Regarding the newly recited claim language “a mixing tip integrally formed as one part with the cartridge...” (claim 51 lines 6-7), it is noted and as also pointed out by Applicant that Wilcox et al. disclose that the mixing tip 54 and the cartridge housing 52/12 are connected by an adhesive, a welding process (Wilcox: Fig. 4; column 5 lines 45-51). The word “integral” is defined as “consisting or composed of parts that together constitute a whole” or “of, pertaining to, or belonging as a part of a whole” (www.dictionary.com). It is maintained that Wilcox’s joining means by an adhesive and especially by a welding process meets the claim language “integrally formed as one part” since such permanent joining means makes the mixing tip 54 and cartridge housing 52 *integral parts of a whole device or forming a whole one piece/part/device*.

Alternatively, if Wilcox, *arguendo*, fails to disclose the mixing tip 54 integrally formed as one part with the cartridge 52, such one piece construction would have been merely a matter of obvious engineering choice that is well within the skill of an artisan. *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). Furthermore, Zwingenberger discloses a syringe comprising a mixing tip 30, head piece 28, and cartridge 22/24 being integrally formed as one part (Figs. 2, 4; abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wilcox et al. by making the mixing tip and the cartridge an integral unit so that it can be inserted into and removed from the syringe and be disposable after its use as taught by Zwingenberger.

As to claims 53-54, Wilcox’s static mixer 56 comprises a mixing helix (column 5 lines 20-22), an outlet tip at the front end of said mixing helix, wherein said outlet tip projects from the front end of the mixing tip. **As to claims 82-84**, Wilcox et al. disclose the cartridge 12 having a

Art Unit: 3732

substantially circular circumferential outer surface with the compartments 50 arranged concentrically. **As to claim 89**, the syringe may be pre-filled with a multi-component dental material (column 1 lines 40-50).

ii. Claims 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilcox or Wilcox in view of Zwingenberger, and further in view of Pauser et al. (2004/0262332 A1).

As to claims 52-55, Wilcox/Zwingenberger disclose the invention substantially as claimed except for the static mixer 56 being collapsible and having a closure plug at its rear end. Pauser et al. disclose a syringe having a helix static mixer 5 that is collapsible (Fig. 3) and having a closing or sealing elements 11 at its rear end for closing the cartridge 6 (Fig. 1; paragraph 106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wilcox/Zwingenberger by incorporating such closing or sealing plugs/elements at the rear end of the static mixer in order to seal the cartridge before use, preventing damage or contamination to the material inside the cartridge. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wilcox/Zwingenberger by making the helix static mixer collapsible or compressible in order to efficiently empty all the material from the mixer.

iii. Claims 56-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilcox/Zwingenberger in view of Pauser et al. as applied to claim 55, and further in view of Hunter et al. (6,572,031).

As to claim 56, Wilcox/Zwingenberger/Pauser disclose the invention substantially as claimed except for the static mixer having an outlet tip that projects from the front end of the mixing tip. Hunter et al. disclose a syringe having a static mixer 4 with an outlet tip 6 that projects from the front end 16 of the mixing tip 10/17 (Fig. 4). It would have been obvious to

Art Unit: 3732

one having ordinary skill in the art at the time the invention was made to modify Wilcox/Zwingenberger/Pauser by having the mixer's outlet tip projecting from the front end of the mixing tip as taught by Hunter et al. in order to establish a precise and fine point of delivery of the material. **As to claims 57-59**, Hunter et al. show that the static mixer is accommodated within the mixing tip 10/17; and that the outlet tip 6 of the mixer comprise corresponding retainers (area 5) that prevent the outlet tip from completely extends beyond the mixing tip. Note that such retainers comprise a recess (shoulder) in the wall that catches the projections (tapers) at the circumference of the outlet tip.

As to claims 60-64, Wilcox/Zwingenberger in combination with Pauser and Hunter et al. show that the first and second compartment are connected by a passageway (Wilcox; within area 52), and the plug(s) as provided by Pauser is capable of sealing either one of the compartments; wherein activation of said syringe by said plunger moves the plugs along the longitudinal direction of the syringe in order to free the passageway.

(10) Response to Argument

Regarding the 102 rejection of claim 51 under Wilcox, Appellant argues that Wilcox et al. fail to disclose the claimed limitation "a mixing tip integrally formed as one part with the cartridge" (claim 51 line 4). As noted in the above ground(s) of rejection, the word "integral" is defined as "consisting or composed of parts that together constitute a whole" or "of, pertaining to, or belonging as a part of a whole" (www.dictionary.com). Wilcox et al.'s mixing tip 54 and cartridge housing 52/12 are disclosed to be connected or joined to each other by an adhesive or a welding process (Wilcox: Fig. 4; column 5 lines 45-51). By broadest reasonably interpretation, the examiner maintains that such joining means by an adhesive and especially by a welding process meets the claim language "integrally formed as one part" since such permanent joining

Art Unit: 3732

means makes the mixing tip 54 and cartridge housing 52 *integral parts of a whole device or forming a whole one piece/part/device*.

Appellant reasoned that because Wilcox et al.'s mixing tip 54 is curved at its front end and is blocked by wall 52 at its rear end, the molding core (used in an injection-molding process) cannot be removed. It appears that in this arguments, Appellant relied extensively on the process(es) of manufacturing the claimed structure, i.e. integrally formed by injection-molding with a molding core, removing the core, etc. Firstly, note that such specific process(es) of manufacturing the claimed structure, is not recited in the claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, such specific process(es) in a product-by-process recitation is not given patentable weight in a product claim if the prior shows the product as claimed. It has been held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this present case, the examiner maintains that Wilcox et al. in Figure 4 show the structural limitations "mixing tip 54 integrally formed as one part with the cartridge 52/12" as claimed (102 rejection). Alternatively, if Wilcox et al., *arguendo*, fail to disclose the mixing tip 54 integrally formed with the cartridge 52 as Appellant's invention, Figure 4 of Wilcox et al. shows that such monolithic one-piece construction of mixing tip 54 and cartridge 52/12 would have been merely a matter of obvious engineering choice that is well within the skill of an artisan (alternative 103 rejection). *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

Art Unit: 3732

Regarding the secondary reference Zwingenberger, the Appellant argued that Zwingenberger also fails to disclose the same claimed limitation "a mixing tip integrally formed as one part with the cartridge" (claim 51 line 4). The examiner maintains that Zwingenberger discloses a syringe comprising a mixing tip 30, head piece 28, and cartridge 22/24 being integrally formed as one part (Figs. 1-4; abstract) as claimed. And if Wilcox et al, *arguendo*, fail to disclose the integral mixing tip and cartridge, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wilcox et al. by making the mixing tip and the cartridge an integral unit so that the whole unit can be inserted into and removed from the syringe and be disposable after its use as explicitly taught by Zwingenberger.

Appellant reasoned that there is no realistic way that the device of Zwingenberger could have film tubes and a headpiece that are integrally formed because there are no molding device or other manufacturing system or process known to the Appellant that would prevent material from flowing into all of the various gaps and openings of Zwingenberger's device, and if one could, the resulting device could not be release from the mold. Once again, Appellant relied on features not being recited in the claim and on the process(es) of a product-by-process recitation. The examiner maintains that by broadest reasonable interpretation, Zwingenberger disclose a syringe having a mixing tip 30, head piece 28, and cartridge 22/24 being integrally formed as one inseparably connected constructive unit (Fig. 1; abstract; column 4 lines 28-32) as claimed by Appellant. The specific process(es) of manufacturing such structure, e.g. preventing material from flowing into the various gaps and openings, release from the mold, etc., as concerned by the Appellant are not recited in the claim and would have been process(es) in a product-by-process claim, on which the patentability of a product does not depend. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). *In re Thorpe*, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Art Unit: 3732

Regarding the references of Pauser et al. and Hunter et al., Appellant provided the same arguments that Pauser et al. and Hunter et al. do not disclose the limitation "the mixing tip being integrally formed as one part with the cartridge". The examiner maintains that Wilcox et al. by itself and/or in combination with Zwingenberger already disclose such limitation "integrally formed as one part" as detailed above. Pauser et al. and Hunter et al. were cited for features in claims 52-64, for which the Appellant did not provide arguments.

Finally, in response to applicant's argument that the examiner has combined an excessive number of references (Wilcox et al., and Zwingenberger, and Pauser et al., with yet Hunter et al.), it has been held that reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

In conclusion, there are no deficiencies found in view of the rejections and arguments stated above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
/Hao D Mai/
Examiner, Art Unit 3732

Conferees:

/Cris L. Rodriguez/
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